Statement of Rep. Henry A. Waxman on the
Food and Drug Administration
Reauthorization Act of 2007
September 19, 2007

The legislation we are poised to pass today provides FDA, for the first time, critical tools that the Agency has been desperately lacking in its efforts to protect the American public from unsafe drugs.

This legislation will provide FDA with the ability to require companies to update their drug label with new safety information. Our goal here is to address tragic situations like Vioxx. In that case, because FDA could not compel the company to promptly make a labeling change, the Agency haggled with the company for 14 months before consumers were finally warned about serious cardiac risks in the drug label. This is simply unacceptable.

However, this legislation will make clear that, in giving FDA this labeling change authority, Congress does not intend to impact, in any way, a drug company's responsibility to promptly update its label with safety information on its own accord. Under FDA's current regulations, companies are required to add new warnings to their labels as soon as they learn of new dangers, even if FDA has not yet required the change.

In promulgating those regulations, FDA made a sensible policy choice. FDA recognized that the companies themselves are in the best position to know about risks associated with their own drugs. Logically, then, the companies should also be charged with the duty to make consumers aware of a drug's risk at the earliest possible moment. FDA recognized that drug safety is first and foremost a shared responsibility between the Agency and the company. And, today, Congress is making it clear that we do not mean to disrupt that balance.

This legislation will also give FDA for the first time the authority to require companies to conduct post-market studies and clinical trials of drugs. Another section of the bill creates a mandatory clinical trial registry and results database to increase the transparency of those trials. Both of these provisions will make a critical contribution towards increasing the safety of our drugs once they are on the market.

But I want to express my deep disappointment that this legislation failed to adopt a compromise that would have provided consumers with much-needed relief from the ever-increasing cost of drugs. Today, we are walking away from a critical and very rare opportunity to make some reasonable adjustments to the windfall profits drug companies receive for conducting pediatric studies under the Best Pharmaceuticals for Children Act.

This is not about whether these pediatric studies should be done. We all agree about that. They are being done now. And there is no question that they would continue to be done if we were to cut back slightly on the term of exclusivity for just the blockbuster drugs that are realizing profits many times over the cost of doing pediatric studies. The Senate did this in its

bill and I regret that the compromise agreement we are considering today did not reflect anything from the Senate approach on this issue.

In my view, there simply is no justification for rewarding companies with incentives that are far in excess of the actual costs of the studies themselves—often hundreds of times over.

I also am deeply disturbed that this legislation fails to remove what is an unprecedented sunset on FDA's statutory authority to require pediatric studies under the Pediatric Research and Equity Act. There is no reason Congress needs to keep revisiting this common sense measure that allows FDA to get critical information about whether new therapies are safe and effective for children—FDA quite obviously needs to have the ability to require that new treatments be tested in children. And there need not be any further discussion about that.

So, although I am pleased that we will provide FDA with critical new authorities and resources in this bill today, I must express my deep regret that we failed to take this opportunity to help individuals, businesses, state governments, and insurers who pay the bill for the higher prices that result when generic competition is delayed for these expensive, blockbuster drugs.